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Ordinance on Handling Organisms in Contained Systems (Containment Ordinance, ContainO)

of 9 May 2012 (Status as of 1 January 2020)

The Swiss Federal Council,

on the basis of Articles 29b paragraphs 2 and 3, 29f, 38 paragraph 3, 39 paragraph 1, 41 paragraphs 2 and 3, 44 paragraph 3, 46 paragraphs 2 and 3, 48 paragraph 2 and 59b of the Environmental Protection Act of 7 October 1983¹ (EPA), and Articles 10 paragraph 2, 14, 19, 20, 24 paragraphs 2 and 3, 25 and 34 of the Gene Technology Act of 21 March 2003² (GTA), on Articles 26 paragraphs 2 and 3, 29 and 78 paragraph 1 of the Epidemics Act of 28 September 2012³ and in implementation of Articles 8 letters g, h and l as well as 19 paragraph 4 of the Convention of 5 June 1992⁴ on Biological Diversity,⁵

ordains:

Chapter 1 General Provisions

Art. 1 Aim

This Ordinance is intended to protect human beings, animals and the environment, as well as biological diversity and its sustainable use, from hazards or harm caused by handling organisms, their metabolic products and wastes in contained systems.

Art. 2 Subject matter and scope of application

¹ This Ordinance regulates the handling of organisms, in particular genetically modified, pathogenic or alien organisms, in contained systems.

² The transport of organisms intended for handling in contained systems is governed by Articles 4, 15 and 25 only.

AS 2012 2777

¹ SR 814.01

² SR 814.91

³ SR 818.101

⁴ SR 0.451.43

⁵ Amended by No I of the O of 27 Sept. 2019, in force since 1 Jan. 2020 (AS 2019 3131).

³ Handling organisms in the environment is governed by the Release Ordinance of 10 September 2008⁶.

⁴ The protection of people and the environment against serious damage resulting from major accidents involving microorganisms is regulated by the Major Accidents Ordinance of 27 February 1991^{7,8}

⁵ The protection of employees when handling microorganisms is governed by the Ordinance of 25 August 1999⁹ on the Protection of Employees from Dangerous Microorganisms.

⁶ This Ordinance does not apply to the handling of organisms:

- a. in accordance with the Ordinance of 20 September 2013¹⁰ on Clinical Trials in Human Research;
- b. in the case of personal use of medical devices for the purposes of in-vitro diagnostics, the dispensing of which is authorised in accordance with Article 17 paragraph 3 of the Medical Devices Ordinance of 17 October 2001^{11,12}

Art. 3 Definitions

In this Ordinance:

- a. *organisms* means cellular or non-cellular biological entities capable of replication or of transferring genetic material, and in particular animals, plants and microorganisms. Mixtures, articles and products containing such entities are also regarded as organisms;
- b. *microorganisms* means microbiological entities, in particular bacteria, algae, fungi, protozoa, viruses and viroids; cell cultures, parasites, prions and biologically active genetic material are also regarded as microorganisms;
- c. *small invertebrates* means arthropods, annelids, nematodes and flatworms;
- d. *genetically modified organisms* means organisms in which the genetic material has been altered by methods of gene technology in accordance with Annex 1 in a way that does not occur under natural conditions by crossing or natural recombination, as well as pathogenic or alien organisms that have also been genetically modified;
- e. *pathogenic organisms* means organisms that can cause diseases in human beings, domesticated animals and plants, in wild flora or fauna or other organisms, as well as alien organisms that are also pathogenic;

⁶ SR **814.911**

⁷ SR **814.012**

⁸ Amended by No III 2 of the O of 29 April 2015, in force since 1 June 2015 (AS **2015** 1337).

⁹ SR **832.321**

¹⁰ SR **810.305**

¹¹ SR **812.213**

¹² Amended by No I of the O of 27 Sept. 2019, in force since 1 Jan. 2020 (AS **2019** 3131).

- f. *alien organisms* means organisms of a species, sub-species or lower taxonomic level that:
 - 1. do not naturally occur in Switzerland or in other EFTA and EU member states (not including overseas areas), and
 - 2. have not undergone selection for use in agriculture or horticultural production to such an extent that their viability in the wild is reduced;
- g. *invasive alien organisms* means alien organisms of which it is known or must be assumed that they will spread in Switzerland and could achieve such a high population density that biological diversity or its sustainable use could be harmed or human beings, animals and the environment could be endangered;
- h. *contained system* means a system that uses physical barriers or a combination of physical and chemical or biological barriers to limit or prevent contact between organisms and people or the environment;
- i. *handling* means any deliberate activity involving organisms, and in particular use, processing, propagation, modification, detection, transport, storage or disposal;
- j.¹³ *improper use* means the handling of organisms subject to a containment obligation which illegally and intentionally endangers or harms humans, animals, the environment or biological diversity and their sustainable use.

Chapter 2

Requirements for Handling Organisms in Contained Systems

Section 1 General Requirements

Art. 4 Duty of care

¹ Any person handling organisms in contained systems must take all due care to ensure that organisms, their metabolic products or wastes:

- a. cannot endanger people, animals or the environment;
- b. do not harm biological diversity or its sustainable use.

² The relevant regulations and the distributor's instructions and recommendations must be observed.

³ Compliance with the duty of care must be clearly documented. The documentation must be retained for ten years following the conclusion of the activity and must be made available on request to the enforcement authorities.

¹³ Amended by No I of the O of 27 Sept. 2019, in force since 1 Jan. 2020 (AS 2019 3131).

Art. 5 Containment obligation and prior assessments

¹ The following organisms must be handled only in contained systems unless they may be handled in the environment in accordance with the Release Ordinance of 10 September 2008¹⁴, the Plant Protection Products Ordinance of 12 May 2010¹⁵ or the Biocidal Products Ordinance of 18 May 2005¹⁶:

- a. genetically modified organisms;
- b. pathogenic organisms;
- c.¹⁷ organisms subject to a containment obligation:
 1. alien small invertebrates,
 2. invasive alien organisms as defined in Annex 2 of the Release Ordinance, and
 3. harmful organisms that are considered particularly dangerous in accordance with the Ordinance issued by the Federal Department of Economic Affairs, Education and Research and the Federal Department of the Environment, Transport, Energy and Communications based on Articles 4 paragraph 3, 24 paragraph 2 and 29 paragraph 2 of the Plant Health Ordinance of 31 October 2018¹⁸, and organisms that are considered potential quarantine organisms in accordance with the Ordinance issued by the Federal Office for Agriculture (FOAG) and the Federal Office for the Environment (FOEN) based on Article 5 paragraph 2 of the Plant Health Ordinance.

² Any person who handles organisms in contained systems must first determine and assess the risk of the occurrence of the organisms (allocate the organisms to a group) and thereafter determine and assess the risk due to the planned activities with the organisms (classify the activities).

³ Any person who handles genetically modified animals and plants in contained systems must first ensure by weighing the interests in accordance with Article 8 GTA that the dignity of living beings is respected.

Art. 5a¹⁹ Primary detection outside contained systems

¹ Where a pathogenic organism with the potential to do considerable harm naturally occurs on a frequent basis, is released intentionally or unintentionally or if it is suspected that it has been released, its primary detection may take place exceptionally outside of contained systems if:

- a. there is no threat to humans, animals, the environment or biological diversity;

¹⁴ SR **814.911**

¹⁵ SR **916.161**

¹⁶ SR **813.12**

¹⁷ Amended by Annex 8 No 4 of the Plant Health Ordinance of 31 Oct. 2018, in force since 1 Jan. 2020 (AS **2018** 4209).

¹⁸ SR **916.20**

¹⁹ Inserted by No 1 of the O of 27 Sept. 2019, in force since 1 Jan. 2020 (AS **2019** 3131).

- b. the analyses are carried out in order help an assessment of the situation;
- c. appropriate security measures are respected; and
- d. the rapid detection systems used can be shown to be reliable.

² Detection as defined in paragraph 1 is only permissible if carried out by employees of the following competent authorities who possess the requisite specialist expertise:

- a. the cantonal emergency services for B-incidents in accordance with Article 3 letter e of the Ordinance of 29 April 2015²⁰ on Microbiological Laboratories;
- b. the competent veterinary authorities responsible for measures to combat disease in accordance with Article 63 of the Epizootic Diseases Ordinance of 27 June 1995²¹;
- c. the federal or cantonal plant protection services responsible for preventive measures in accordance with Article 10, for monitoring in accordance with Article 18 and for surveying in accordance with Article 19 of the Plant Health Ordinance of 31 October 2018²² (PHO);
- d. the establishments authorised in accordance with Article 76 PHO to conduct assessments in accordance with Article 84 PHO.

Art. 6 Grouping of organisms

¹ In order to determine the risk of an occurrence of organisms, the extent and probability of harmful effects to human beings, animals or the environment and to biological diversity and its sustainable use must be estimated. In doing so, the criteria in Annex 2.1 number 1 must be taken into account.

² In order to assess the risks determined, the organisms must be allocated to one of the following groups according to the criteria in Annex 2.1 number 2:

- a. Group 1: organisms whose occurrence presents no risk or a negligible risk;
- b. Group 2: organisms whose occurrence presents a low risk;
- c. Group 3: organisms whose occurrence presents a moderate risk;
- d. Group 4: organisms whose occurrence presents a high risk.

³ If certain organisms have already been grouped according to the list in Article 26, no new risk determination and assessment need be carried out unless there are indications of an increased or reduced risk in an occurrence of these organisms. In the event of significant new findings, the risk must be determined and assessed again.

²⁰ SR 818.101.32

²¹ SR 916.401

²² SR 916.20